IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
SOUTHERN DIVISION

SHIRLEY GROSS, Plaintiff, v. PFIZER, INC., *et. al*, Defendants.	Civil Action No. 10-CV-00110-AW

MEMORANDUM OPINION

Pending before the Court is Plaintiff Shirley Gross's motion to alter or amend the Court's November 22, 2011 Order granting Defendant PLIVA's motion for judgment on the pleadings. *See* Doc. No. 88. The Court has reviewed the motions and all supporting documents and finds no hearing is necessary. *See* MD. LOC. R. 105.6 (D. Md. 2010). For the reasons articulated below, the Court DENIES Plaintiff's Motion.

I. FACTUAL & PROCEDURAL BACKGROUND

Plaintiff filed this action as a result of injuries she suffered from ingesting the prescription drug metoclopramide. Plaintiff stipulates that the drugs she consumed are a generic form of metoclopramide manufactured by Defendant PLIVA, and that she did not ingest any metoclopramide product manufactured by Pfizer, Wyeth or Schwarz. *See* Doc. No. 54. Plaintiff nonetheless filed suit against Defendants Pfizer, Wyeth, and Schwarz, who manufactured the brand-name form of metoclopramide, on theories of negligence, breach of warranty, strict

product liability, and misrepresentation. The Court dismissed Plaintiff's claims against the brand-name manufacturers because Maryland law only allows drug defect claims to proceed against the manufacturer whose drug allegedly caused the injury; in this case, the generic manufacturer PLIVA. *See* Doc. No. 63.

On April 7, 2011, the Court stayed proceedings against PLIVA pending the Supreme Court's decision in a collection of lawsuits addressing claims against generic manufacturers based on similar facts. On June 23, 2011, the Supreme Court decided *Pliva, Inc. v. Mensing*, 564 U.S. - - -, 131 S.Ct. 2567, 180 L.Ed.2d 580 (2011) (*reh'g denied*). In *Mensing*, the Supreme Court considered a state law tort claim based on the alleged failure of a manufacturer to provide adequate warning labels for generic metoclopramide. 131 S.Ct. at 2572. Under the Food and Drug Administration ("FDA") regulations, generic drug manufactures are required to make their warning labels identical to those provided by the brand-name manufacturers. *Id.* at 2577. Because FDA regulations do not allow generic manufacturers to independently change or strengthen their product labeling, the Court found that it would be impossible for a generic manufacturer to comply with both federal law and state tort law. *Id.* at 2578. As a result, the Court held that the federal regulations preempt state law failure to warn claims, reversing decisions by the Fifth and Eighth Circuit Courts of Appeals which had found otherwise. *Id.*

After the *Mensing* decision, Plaintiff filed a motion in the instant action to alter or amend the Court's entry of final judgment in favor of brand-name manufacturer Defendants as well as a motion to lift stay. *See* Doc. Nos. 74, 76. The Court denied Plaintiff's motion to reconsider its judgment in favor of the brand-name manufacturers but granted her motion to lift stay for the limited purpose of allowing the parties to brief the Court on the impact of the *Mensing* decision. *See* Doc. No. 80. Subsequently, PLIVA filed a motion for judgment on the pleadings, contending

that Plaintiff's state-law claims against PLIVA are preempted post-*Mensing*. The Court agreed and, on November 22, 2011, granted PLIVA's motion. On December 20, 2011, Plaintiff filed the present motion to alter or amend the Court's November 22, 2011 judgment, contending that reconsideration is necessary to correct errors of law and prevent manifest injustice. *See* Doc. No. 88.

II. STANDARD OF REVIEW

Under Rule 59(e), a Court can amend an earlier judgment: "(1) to accommodate an intervening change in controlling law; (2) to account for new evidence not available at trial; or (3) to correct a clear error of law or prevent manifest injustice." *Hutchinson v. Stanton*, 994 F.2d 1076, 1081 (4th Cir. 1993). Reconsideration is, however, an extraordinary remedy. *Pac. Ins. Co. v. Am. Nat'l Fire Ins. Co.*, 148 F.3d 396, 403 (4th Cir. 1998).

III. ANALYSIS

Plaintiff seeks reconsideration of the Court's order granting PLIVA's motion for judgment on the pleadings, contending that she retains claims against PLIVA under theories of strict liability, negligence, breach of warranties, fraud, and misrepresentation post-*Mensing* and that new cases offer additional support for the viability of her claims. Plaintiff's arguments in support of her motion overwhelmingly constitute a rehash of prior arguments already considered and rejected by this Court. Additionally, Plaintiff's contention that "the vast majority of courts" are not dismissing similar claims across the country is belied by the case law. Most notably, the Sixth Circuit earlier this month denied a petition for a rehearing and rehearing en banc by plaintiffs who have made and continue to make substantially the same arguments as does

Plaintiff in the instant action. *See Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011) *petition for reh'g and reh'g en banc denied* (6th Cir. Nov. 22, 2011) (Doc. No. 89 Ex. 3); Pls.'-Appellants' Supplemental Letter Br. Regarding *Pliva, Inc. v. Mensing* (Doc. No. 83 Ex. 9); Pls.'-Appellants' Pet. for Reh'g and Reh'g En Banc (Doc. No. 89 Ex. 8).

At the time of the Court's November 22, 2011 judgment, it noted the growing number of district courts dismissing similar lawsuits against generic drug manufacturers in the wake of *Mensing. See* Doc. No. 86 at 8-9 (citing district court cases). In the intervening two months, the number of courts dismissing similar suits under *Mensing* has only grown. *See, e.g.*, *Del Valle v. PLIVA, Inc.*, Civ. No. B: 11-113 (S.D. Tex. Dec. 21, 2011) (Doc. No. 89 Ex. 2) (finding that plaintiff's "claims against the generic drug defendants, no matter how she casts them, are for failure to warn" and that "[v]irtually every district court in the country that has examined Reglan/metoclopramide claims, after *Mensing*, has concluded that the Supreme Court's decision mandates dismissal of claims against makers of generic drugs for failing to unilaterally include adequate warnings."); *Huck v. Trimark Physicians Grp.*, No. LAC018947 (Iowa Dist. Ct. Sac Cnty. Jan. 5, 2012) (Doc. No. 89 Ex. 4) (dismissing plaintiff's claims for breach of warranty, negligence, negligent misrepresentation, fraud, constructive fraud, and fraud by concealment, under *Mensing*); *Guarino v. Wyeth LLC*, No. 8:10-cv-02885-T-30TGW (M.D. Fla. Jan. 5, 2012) (Doc. No. 89 Ex. 5) (denying plaintiff's motion for reconsideration on its claims against generic manufacturer for negligence, strict liability, breach of warranties, misrepresentation, fraud, and negligence per se, noting that "recently over twenty additional decisions have been entered dismissing materially identical claims in the face of the same or similar arguments Plaintiff presents in this case.").

However, Plaintiff is correct in identifying a split in authority as to the viability of Plaintiff's claims based on PLIVA's failure to include a warning on its metoclopramide label that the brand-name manufacturer had added to its label in 2004. Pre- July 2004, the brand-name label and generic label both stated: "Therapy longer than 12 weeks has not been evaluated and cannot be recommended." In July 2004, the brand-name label added to that already-existing language the statement: "Therapy should not exceed 12 weeks in duration." PLIVA did not add this language to the label of the generic metoclopramide consumed by Plaintiff. Plaintiff argues that its claim based on the 2004 label change is not preempted because it does not require the generic manufacturer to send "substantial new warning information" or "additional warnings" but only requires that the generic manufacturer inform physicians and consumers of warnings consistent with and not contrary to information on the brand-name label.

A few courts have allowed similar claims based on the 2004 label change to proceed, finding that they are not preempted under *Mensing*. *See, e.g.*, *Fisher v. Pelstring*, Civ. No. 4:09-cv-00252-TLW, 2011 WL 4552464, at *3 (D.S.C. Sept. 30, 2011) ("The Court finds that this possible deviation in PLIVA's label for generic metoclopramide, which both parties indicate exists, is sufficient to conclude the plaintiffs' claims are not entirely preempted."); *Brasley-Thrash v. Teva Pharm. USA, Inc.*, Civ. No. 10-00031-KD-N (S.D. Ala. Sept. 12, 2011) (Doc. No. 88 Ex. 6 at 5) ("[A]t this time, the defendants have not convinced this Court that generic drug manufacturers must seek out the FDA's approval when sending a DHCP letter that simply reiterates warnings contained in the approved label.").

The cases cited by Plaintiff have not been issued since the Court's November 22, 2011 opinion; nor do they change the Court's analysis of Plaintiff's claim. The Court did not dismiss Plaintiff's claim relating to the 2004 label change on the grounds of preemption, although there

are strong arguments that such a claim is preempted, and the Sixth and Eighth Circuits have rejected nearly identical arguments by plaintiffs after *Mensing*. *See, e.g., Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011) *petition for reh'g and reh'g en banc denied* (6th Cir. Nov. 22, 2011) (Doc. No. 89 Ex. 3); Pls.'-Appellants' Pet. for Reh'g and Reh'g En Banc (Doc. No. 89 Ex. 8) (denying plaintiff's petition for rehearing and rehearing en banc despite Plaintiff's argument that "*Mensing* did not address PLIVA's failure to implement the 2004 label change", noting that "the issues raised in the petition were fully considered upon the original submission and decision of the cases.")

Rather, the Court dismissed this claim in its November 22, 2011 opinion because Plaintiff's allegations relating to the 2004 label change failed to state a claim upon which relief can be granted. *See* Doc. No. 86 at 8 ("However, Plaintiff does not claim that the alleged failure of PLIVA to update its label gives rise to any cause of action under Maryland law … ."). Within her Complaint and subsequent pleadings, Plaintiff has consistently alleged that all metoclopramide labels, including the brand-name label with the added language "[t]herapy should not exceed 12 weeks in duration", were inadequate until an FDA labeling change in 2009. Plaintiff now contends that her injuries could have been avoided if PLIVA had given physicians and consumers this inadequate warning. As the court noted in *Del Valle v. PLIVA* when faced with the same claim, "[i]n essence, [plaintiff] is asking the Court to hold PLIVA and Teva responsible for not updating their labeling in 2004 to a label that [plaintiff] believes, and has pled, would still be inadequate." Civ. No. B: 11-113 (S.D. Tex. Dec. 21, 2011) (Doc. No. 89 Ex. 2 at 14). Given the irreconcilable inconsistency between what Plaintiff has pled and her present theory of relief (or lack thereof, as the Court noted in its prior opinion), dismissal of Plaintiff's

claim relating to the 2004 label change is proper regardless of the district and circuit court split on the issue of whether *Mensing* preempts such claims.

Although the Court saw fit to clarify its rationale for rejecting Plaintiff's claim relating to the 2004 label change, the Court reiterates that Plaintiff has shown no error of law or change in controlling law that would give the Court pause to reconsider its judgment; indeed, portions of Plaintiff's most recent motion are taken nearly verbatim from her response to PLIVA's motion for judgment on the pleadings. The standard for Rule 59(e) motions is high. To justify reconsideration on the basis of manifest error, the prior decision cannot be "'just maybe or probably wrong; it must . . . strike us as wrong with the force of a five-week-old, unrefrigerated dead fish.'" *TFWS, Inc. v. Franchot*, 572 F.3d 186, 194 (4th Cir. 2009) (quoting *Bellsouth Telesensor v. Info. Sys. & Networks Corp.*, Nos. 92-2355, 92-2437, 1995 WL 520978 at * 5 n.6 (4th Cir. Sept. 5, 1995)). Plaintiff's motion does not meet this sniff test; her reiteration of arguments reveals a "mere disagreement" with the Court's decision and is insufficient grounds for such an extraordinary remedy. *Hutchinson v. Staton*, 994 F.2d 1076, 1082 (4th Cir. 1993). Accordingly, the Court affirms its November 22, 2011 opinion in all respects.

IV. CONCLUSION

For the foregoing reasons, Plaintiff's motion for reconsideration under Federal Rule 59(e) is DENIED. A separate Order will follow.

January 27, 2012
Date

/s/
Alexander Williams, Jr.
United States District Judge